ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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July 1, 2014

Centers for Medicare & Medicaid Services
Department of
Health and Human Services
Attention: CMS–1609–P
P.O. Box 8010
Baltimore, MD 21244–8010

To whom it may concern:

The American Society of Nephrology (ASN), the world's leading organization of kidney health professionals, represents nearly 15,000 health professionals who are committed to treating and studying kidney disease and to improving the lives of patients affected by kidney disease. ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney disease. ASN is pleased to have the opportunity to provide comments regarding the FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice Proposed Rule.

In summary, ASN urges CMS to:

- Recognize the role of dialysis in providing a comfortable end of life for end-stage renal disease (ESRD) patients with unrelated terminal conditions.
- Continue to permit dialysis patients with terminal conditions not related to ESRD and a life expectancy less than six months who are receiving dialysis to continue to do so, and continue to allow hospice agencies to provide hospice services to patients who wish to continue dialysis treatment. ASN urges CMS to specify in the final rule that existing policy in the Medicare Benefit Policy Manual Chapter 11 (described in greater detail below) remains in place.
- Consider, in the longer term, conducting a demonstration project to test the feasibility, acceptability and effectiveness of concurrent dialysis and hospice care for addressing the palliative care needs of ESRD patients with limited life expectancy who wish to receive both services.

ASN strongly advises that CMS continue to support the eligibility of dialysis patients with non-ESRD-related terminal diagnoses to receive Medicare covered services under both the Medicare ESRD and Hospice programs

Preserving access to hospice care for ESRD patients with non-ESRD terminal conditions

ASN is concerned that, if finalized, CMS' proposed changes to the definition of terminal illness and related conditions would make it difficult to continue providing the best possible care to terminally ill patients with kidney failure. As noted above, more than 3,000 patients on dialysis currently receive hospice care annually for non-renal related terminal diagnoses.

Current policy as articulated in the "Medicare Benefit Policy Manual Chapter 11 - End Stage Renal Disease" states that "If the patient's terminal condition is not related to ESRD, the patient may receive covered services under both the ESRD benefit and the hospice benefit. Hospice agencies can provide hospice services to patients who wish to continue dialysis treatment." ASN is concerned that the proposed changes would contradict this important policy protecting dialysis patients' access to hospice services for care for non-ESRD-related terminal conditions.

ASN urges CMS to ensure in the final rule that current policy in the Medicare Benefit Policy Manual Chapter 11 remains in place, such that patients with terminal conditions not related to ESRD may continue to receive full dialysis care under the Medicare ESRD program at the same time as receiving hospice care, and that hospice agencies can continue to enroll patients who wish to continue dialysis treatment.

In the longer term, ASN recommends that CMS consider a demonstration project to test the feasibility, acceptability and impact of allowing for concurrent receipt of dialysis and hospice services for the broader population of patients with ESRD who have a life expectancy of less than six months who wish to receive these services.

Recognizing Intent of the Proposed Changes

ASN recognizes the need for CMS to prevent fraud and waste and to control healthcare costs—and the society appreciates that the changes proposed in the rule are intended to preserve the availability of the hospice benefit for Medicare beneficiaries in the future. ASN also agrees that, currently, there is substantial fragmentation of care for terminally ill patients under Medicare. In complex patients, multiple different diagnoses and conditions may contribute to limited life expectancy making it difficult to identify a single "terminal" illness. In this context, the society understands the rationale for CMS's goal of uncoupling hospice eligibility from specific terminal diagnoses and consolidating services for terminally ill patients who have elected to receive hospice under the Medicare Hospice Program. **However, because dialysis can be a beneficial palliative treatment, ASN urges CMS to continue to allow patients with non-ESRD-related terminal diagnoses on dialysis continue to receive covered services under both the ESRD benefit and the hospice benefit.**

That said, ASN encourages CMS to conduct monitoring and oversight activities to ensure the hospice benefit is used appropriately, and to prevent fraud and waste. The society specifically encourages patient-centric monitoring efforts to guarantee that the benefit is applied in a way that is meaningful and appropriate for patients.

Importance of hospice care for patients with ESRD

ASN is concerned that the proposed changes will have unintended adverse consequences for patients receiving long-term dialysis—a population for whom there is already a large unmet need for hospice care at the end of life. Patients with ESRD on dialysis have both a high mortality rate (an adjusted mortality rate of 6.4 – 7.8 times higher than the age-matched general population, with cardiovascular disease being the most common cause of death) and a high symptom burden. Compared with Medicare beneficiaries with other chronic conditions, older patients receiving long-term dialysis spend more time in the hospital and intensive care unit during the final month of life, are more likely to receive intensive procedures intended to prolong life and are 1.5 – 2 times more likely to die in the hospital.

Consensus exists within the nephrology and palliative care communities that these patients need *more not less* access to palliative and hospice care. At present, only patients with ESRD whose renal disease is not considered to be their life-limiting diagnosis can continue to receive dialysis after enrolling in hospice. Approximately 3,000 patients are currently receiving concurrent hospice and dialysis services under this policy. If the proposed rule is finalized, these patients would likely need to choose between continuing dialysis and receiving hospice care.

The goal of palliative care, including hospice, is to achieve a "good death" for the patient that minimizes suffering and respects the patient's and family's wishes, priorities and cultural preferences. It is important to recognize that while dialysis is often deployed within a "curative" treatment paradigm in order to extend life, dialysis can also provide palliation and can be a useful adjunct to hospice care in patients with limited life expectancy. Discontinuation of dialysis in a patient with no residual renal function will lead to certain death within less than two weeks in the vast majority of patients, and may result in an escalation of uremic symptoms.

Dialysis treatments may improve distressing symptoms such as shortness of breath, itching, confusion, neuropathy, and nausea. Discontinuing dialysis thus carries the potential to increase—rather than decrease—symptom burden and palliative care needs in individual patients. Further, having to choose between continuing long-term dialysis care and electing for hospice care may cause undue psychological distress in a terminally ill patient and his or her family. ASN believes that it would be inappropriate to ask a patient with ESRD to discontinue dialysis in order to access hospice if dialysis could help to relieve suffering in that patient.

For these reasons, ASN encourages CMS to identify strategies to continue to ensure access to hospice care for patients on dialysis who are suffering from unrelated terminal conditions and, in the future, to explore the possibility of increasing access to hospice care for the broader population of patients with ESRD with a life expectancy of less than six months.

Significance of Dialysis Costs in the Hospice Environment

In lieu of any indication in this proposed rule that CMS would alter the hospice bundle (or provide a hospice bundle add-on) to allow for provision of dialysis care for patients in hospice for non-ESRD-related terminal conditions, ASN is concerned that patients would now have to choose between either the Medicare hospice benefit or the Medicare ESRD benefit. Because dialysis is an expensive service unlikely to be affordable within the budgets of most hospice organizations (and the Medicare Hospice Program more broadly), the proposed changes could effectively make patients choose between discontinuing dialysis and receiving hospice services.

Hospices are paid approximately $150 per day ($4,500 per month) for routine home hospice care, which covers all drugs, equipment and services related to the terminal illness. Dialysis costs about $3,224 per month (12 treatments at $248 per treatment). As CMS notes in the proposed rule, the annual per-beneficiary cap amount for 2013 was set at $26,157. The average annual cost of dialysis care would total approximately $38,688: most hospices simply could not afford to cover the cost of dialysis under the current rates.

However, ASN believes the overall cost of care is likely to be lower if Medicare permits patients to continue dialysis after electing for hospice care. Although dialysis treatments are costly, inpatient costs account for the vast majority of end-of-life costs for this population. Disallowing simultaneous hospice care for dialysis patients with a life expectancy of less than six months would mean many patients opt out of hospice and continue in a "curative" dialysis care model.

Outside of the hospice environment, many of these patients would experience frequent acute care hospital admissions and aggressive, invasive, and expensive interventions intended to prolong life. ASN believes that overall Medicare costs are likely to be lower if patients continue to have the option to receive dialysis after electing for hospice, as more patients on dialysis with non-ESRD-related terminal conditions could continue to receive hospice care

Challenges to providing end-of-life care in the dialysis environment

The hospice care environment and the multidisciplinary team approach that is integral to the hospice model are uniquely positioned to address the complex end-of-life needs of ESRD patients. Nephrology providers and dialysis unit staff are inadequately prepared to address the complex care needs of dying patients. Given the shortage of palliative care physicians in the United States, it is unrealistic to expect that dialysis patients approaching the end of life will be able to receive high quality palliative care in non-hospice settings at the present time. If this proposal is finalized and patients with ESRD must choose between hospice care and dialysis care, many patients who would otherwise benefit from the symptom management, spiritual care and other end of life management expertise that hospice care entails are unlikely to be able to access these services in other settings.

Finally, ASN observes that the quality reporting for hospices sounds reasonable and in alignment with other initiatives to decrease payment and increase quality, but it would be imperative for ASN and other stakeholders to receive more details regarding the metrics proposed and have opportunity for public comment.

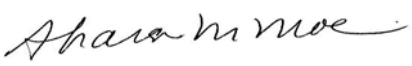
Conclusion

In conclusion, ASN recommends that CMS takes steps to ensure that patients with limited life expectancy whose terminal conditions are not related to ESRD continue to be eligible to receive covered services under both the ESRD benefit and the hospice benefit. The final rule should clarify this policy and ensure that hospice agencies can provide hospice services to patients who wish to continue dialysis treatment. In the longer term, CMS should consider a demonstration project to test the feasibility, acceptability and impact of concurrent receipt of hospice and dialysis services for the broader population of patients with ESRD with a life expectancy of less than six months.

The society hopes that the recommendations it offers in this letter are helpful, and stands ready to discuss these comments. ASN welcomes the opportunity to continue to collaborate with CMS in further improving and assuring patient access to both dialysis and hospice care.

Again, thank you for your time and consideration. To discuss ASN's comments, please contact ASN Manager of Policy and Government Affairs at rmeyer@asn-online.org or at (202) 640-4659.

Sincerely,



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